IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	MDL NO. 3094 THIS DOCUMENT RELATES TO ALL CASES JUDGE KAREN SPENCER MARSTON
DENISE LOPEZ-PERALES, *Plaintiff,* v. NOVO NORDISK A/S, NOVO NORDISK INC., and ELI LILLY AND COMPANY, *Defendants.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: 2:25-cv-2162

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the Western District of Texas as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

X Plaintiff currently resides in San Antonio, TX (City/State).

X Plaintiff purchased and used Defendant(s)' products in San Antonio, TX (City/State).

__ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

X The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)):
Western District of Texas.

__ There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1391(b)(3)).

__ Other reason (please explain): _____.

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, DENISE LOPEZ-PERALES, who was severely injured as a result of Plaintiff's use of Ozempic and Trulicity, injectable prescription medications that are used to control blood sugar and to reduce cardiovascular risk in adults with type 2 diabetes.

2. Ozempic is also known as semaglutide.

3. Trulicity is also known as dulaglutide.

4. Ozempic and Trulicity work by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

5. Ozempic and Trulicity belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

6. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendants have downplayed the severity of the gastrointestinal events caused by its GLP-1RAs, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") and its sequelae.

7. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites,

[1] *See, e.g.*, CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).

undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.[2]

PARTY PLAINTIFF

8. Plaintiff, DENISE LOPEZ-PERALES, is a citizen of the United States, and is a resident of the State of Texas.

9. Plaintiff is 51 years old.

10. Plaintiff used Ozempic from approximately June 2021 to October 2021.

11. Plaintiff used Trulicity from approximately August 2022 to September 2022.

12. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Ozempic and Trulicity that Plaintiff used.

13. As a result of using Ozempic and Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

14. As a result of using Ozempic and Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae, which resulted in, for example, nausea, severe abdominal pain, severe vomiting, and requiring emergency medical care to treat severe abdominal pain and vomiting.

PARTY DEFENDANTS

15. Defendant Novo Nordisk Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

[2] *Gastroparesis*, Mayo Clinic (June 11, 2022), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (visited on 9/26/23).

16. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

17. Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic's label.[3]

18. Defendants Novo Nordisk Inc., and Novo Nordisk are referred to collectively herein as "Novo Nordisk."

19. Novo Nordisk designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic.

20. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

21. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[4]

22. Novo Nordisk and Eli Lilly are collectively referred to herein as "Defendants".

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

23. On December 5, 2016, Novo Nordisk announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the

[3] Ozempic prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79 (visited on 9/26/23).
[4] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

announcement, Novo Nordisk represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[5]

24. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[6]

25. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[7] On January 16, 2020, the FDA approved sNDA 209637/S-003.[8]

26. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.[9]

B. FDA's Approval of Trulicity

27. On September 18, 2014, the FDA approved Eli Lilly's Biologics License Application ("BLA") for dulaglutide "as an adjunct to diet and exercise to improve glycemic

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[5] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (visited on 9/26/23).

[6] FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (visited on 9/26/23).

[7] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (visited on 9/26/23).

[8] FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (visited on 9/26/23).

[9] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (visited on 9/26/23).

control in adults with type 2 diabetes mellitus" to be marketed as Trulicity in "single dose pre-filled syringes and pre-filled pens." As initially approved, the recommended dose for Trulicity was 1.5 mg per week.[10]

28. On April 19, 2019, Eli Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[11]

29. On November 4, 2019, Eli Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 per week) of Trulicity. On September 3, 2020, the FDA approved that request.[12]

30. On May 17, 2022, Eli Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes mellitus." On November 17, 2022, the FDA approved the drug for pediatric use.[13]

C. Novo Nordisk's Marketing and Promotion of Ozempic

31. On December 5, 2017, Novo Nordisk announced the FDA's approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: "Novo Nordisk expects to launch OZEMPIC® in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC® will be priced at parity to current market-leading weekly GLP-1RAs and will be offered with a savings card program to reduce co-pays for eligible

[10] FDA Approval Letter for BLA 125469/0 (Sept. 18, 2014), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf (last visited Nov. 8, 2023).
[11] FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s033ltr.pdf (last visited Nov. 8, 2023).
[12] *See News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).
[13] FDA Approval Letter for BLA 125469/S-051 (Nov. 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf (last visited Nov. 15, 2023).

commercially-insured patients. Additionally, as part of the access strategy, Novo Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions."[14]

32. On February 5, 2018, Novo Nordisk announced that it had started selling Ozempic in the United States and touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[15]

33. Novo Nordisk promoted the safety and sale of Ozempic in the United States on its websites, in press releases, through in-person presentations, through the drug's label, in print materials, on social media, and through other public outlets.

34. On July 30, 2018, Novo Nordisk launched its first television ad for Ozempic, to the tune of the 1970s hit pop song "Magic" by Pilot, wherein Novo Nordisk advertised that "adults lost on average up to 12 pounds" when taking Ozempic, even though it is not indicated for weight loss.[16]

35. On March 28, 2022, Novo Nordisk announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release,

[14] *Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes*, Cision PR Newswire (December 05, 2017), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutide-injection-for-the-treatment-of-adults-with-type-2-diabetes-300567052.html (visited on 9/26/23).

[15] *Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes*, Cision PR Newswire (February 05, 2018), available at https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html (visited on 9/26/23).

[16] *Ozempic TV Spot, 'Oh!'*, iSpot.tv (July 30, 2018), available at https://www.ispot.tv/ad/d6Xz/ozempic-oh (visited on 9/26/23).

Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[17]

36. Since 2018, Novo Nordisk has spent more than $884,000,000 on television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.[18]

37. In 2022, Novo Nordisk spent $180.2 million on Ozempic ads, including an estimated $157 million on national television ads for Ozempic, making Ozempic the sixth most advertised drug that year. As a result of its GLP-1RA treatments, including Ozempic, Novo Nordisk forecasts sales growth of 13% to 19% for 2023.[19]

38. On July 6, 2023, it was reported that Novo Nordisk had spent $11 million in 2022 on food and travel for doctors "as part of its push to promote Ozempic and other weight loss-inducing diabetes drugs."[20] The spending bought more than 457,000 meals for almost 12,000 doctors while also flying doctors to places like London, Paris, Orlando, and Honolulu.[21]

39. In an article published on July 21, 2023, the President and CEO of the Alliance of Community Health Plans described Novo Nordisk's spending on meals for doctors as "outrageous" and suggested that the millions Novo Nordisk spent marketing its drugs to prescribers would be better used furthering research about potential side effects and long-term

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[17] *Novo Nordisk receives FDA approval of higher-dose Ozempic® 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (visited on 10/16/23).

[18] Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), available at https://medwatch.com/News/Pharma___Biotech/article15680727.ece (visited on 9/26/23).

[19] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (visited on 9/26/23).

[20] Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic/ (visited on 9/26/23).

[21] Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic/ (visited on 9/26/23).

effectiveness. The author cited research published in the spring of 2023 showing an increased risk of intestinal obstruction as a result of using GLP-1RA drugs.[22]

40. As a result of Novo Nordisk's advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[23] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[24]

41. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[25] and currently has over 1.3 billion views.[26]

42. On June 15, 2023, NBC News published a report about the "thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy." While many of those ads were found to be from online pharmacies, medical spas, and diet clinics, as of June of 2023, Novo Nordisk was still running online social-media ads for its semaglutide products, despite claiming in May that it would stop running ads due to a shortage of the drug.[27]

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[22] Erin Prater, *Ozempic manufacturer Novo Nordisk spent $11 million last year 'wining and dining' doctors. Experts slam the move as a breach of doctor-patient trust,* Fortune Well (July 21, 2023), available at https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travel-prescribing-doctors/ (visited on 9/26/23); *see also* Erin Prater, *Weight-loss drugs like Ozempic and Wegovy may put certain people at risk of serious complications, researchers warn*, Fortune Well (March 7, 2023), available at https://fortune.com/well/2023/03/07/ozempic-wegovy-elevated-risk-intestinal-obstruction-later-type-2-diabetes-weight-loss-drug/ (visited on 10/18/23).

[23] Choi A, Vu H, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (March 17, 2023), available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (visited on 9/26/23).

[24] Gilbert D, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023), available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/ (visited on 9/26/23).

[25] Blum D, *What is Ozempic and Why Is It Getting So Much Attention?,* The New York Times (published Nov. 22, 2022, updated July 24, 2023), available at https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (visited on 9/26/23).

[26] https://www.tiktok.com/tag/ozempic (visited on 11/14/23).

[27] Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (visited on 9/26/23).

43. On July 10, 2023, a global media company declared Ozempic as "2023's buzziest drug" and one of the "Hottest Brands, disrupting U.S. culture and industry."[28]

44. At all relevant times, Novo Nordisk was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

D. Eli Lilly's Marketing and Promotion of Trulicity

45. At all relevant times, Eli Lilly was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Trulicity.

46. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Eli Lilly advertises Trulicity through its websites, press releases, in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of gastroparesis or its sequelae.[29]

47. Upon the approval of Trulicity on September 18, 2014, an Eli Lilly spokesperson indicated that Trulicity "has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."[30] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of gastroparesis or warn of the risk of gastroparesis or

[28] Bain P, *Ozempic was 2023's Buzziest Drug*, AdAge (July 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (visited on 9/26/23).
[29] Eli Lilly and Company 2022 Annual Report, available at https://investor.lilly.com/static-files/2f9b7bb1-f955-448d-baa2-c4343d39ee62 (last visited Nov. 15, 2023).
[30] *Lilly's Trulicity (dulaglutide) Now Available in U.S. Pharmacies,* PR Newswire (Nov. 10, 2014), available at https://www.prnewswire.com/news-releases/lillys-trulicity-dulaglutide-now-available-in-us-pharmacies-282138401.html (last visited Nov. 15, 2023).

its sequelae. Instead, the press release merely indicated that "Trulicity has not been studied in patients with … [pre-existing] gastroparesis."[31]

48. Following the FDA's approval of Trulicity in September 2014, Eli Lilly launched its direct-to-consumer ad campaign in 2015, with print and digital ads first appearing in September 2015 and the first Trulicity television ad launching on October 19, 2015.[32]

49. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity … was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause gastroparesis or its sequelae.[33]

50. In a February 21, 2020, press release announcing Trulicity's new indication for reduction of cardiovascular risk, Eli Lilly touted Trulicity's ability to reduce the risk of major adverse cardiovascular events, including heart attack and stroke, even in adults without established cardiovascular disease.[34] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of gastroparesis, or its sequelae, associated with GLP-1RAs.

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[31] *News Release: FDA Approves Trulicity (dulaglutide), Lilly's Once-Weekly Therapy for Adults with Type 2 Diabetes,* Eli Lilly (Sept. 18, 2014), available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy (last visited Nov. 15, 2023).
[32] Beth Snyder Bulik, *One year after FDA nod, Eli Lilly's Trulicity launches first consumer campaign,* Fierce Pharma (Oct. 19, 2015) https://www.fiercepharma.com/dtc-advertising/one-year-after-fda-nod-eli-lilly-s-trulicity-launches-first-consumer-campaign (last visited Nov. 15, 2023).
[33] *News Release: Trulicity (dulaglutide) demonstrates superiority in reduction of cardiovascular events for broad range of people with type 2 diabetes,* Eli Lilly (Nov. 5, 2018), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-demonstrates-superiority-reduction (last visited Nov. 15, 2023).
[34] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).

51. When announcing the approval of higher weekly doses of Trulicity in September 2020, Eli Lilly's press release indicated that "with the 3.0 and 4.5 [mg] doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their condition progresses."[35] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of gastroparesis or its sequelae.

52. Around this same time, Robert H. Schmerling, MD, Senior Faculty Editor and Editorial Advisory Board Member at Harvard Health Publishing commented that the actors in the television ads for Trulicity appeared notably thinner than the typical person with type 2 diabetes.[36]

53. In Summer 2021, in conjunction with Eli Lilly's sponsorship of the rescheduled Summer Olympics, Eli Lilly ran extensive television ads for Trulicity featuring Olympic gymnast Laurie Hernandez and her father, who has type 2 diabetes. The ad indicates that treatment with Trulicity is the "right choice" for people with type 2 diabetes but does not mention or warn about gastroparesis or its sequelae.[37]

54. In a similar January 2022 television ad featuring Olympic figure skater Madison Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes but did not warn that Trulicity can cause gastroparesis or its sequelae.[38]

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[35] *News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).

[36] Robert H. Schmerling, MD, *Harvard Health Ad Watch: A feel-good message about a diabetes drug,* Harvard Health Publishing (Sept. 18, 2020), available at https://www.health.harvard.edu/blog/harvard-health-ad-watch-a-feel-good-message-about-a-diabetes-drug-2020091620961 (last visited Nov. 15, 2023).

[37] *See* Trulicity TV advertisement, available at https://www.youtube.com/watch?v=eVA1vYV980w (last visited Nov. 15, 2023); Beth Snyder Bulik, *Lilly warms up for Olympics with Team USA athletes in ads for Trulicity, Emgality and Verzenio,* Fierce Pharma (July 7, 2021), available at https://www.fiercepharma.com/marketing/lilly-warms-up-for-olympics-team-usa-athletes-ads-for-trulicity-emgality-and-verzenio (last visited Nov. 15, 2023).

[38] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).

55. In January 2022, the FDA determined that Eli Lilly's "10,800 Minutes" Instagram ad for Trulicity "ma[de] false or misleading claims and representations about the benefits and risks of Trulicity" and that the ad elicits "a misleading impression regarding the safety and effectiveness of Trulicity" that "minimizes the risks associated with the use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account.[39] The FDA citation is emblematic of Eli Lilly's willingness to mislead and omit important information, focusing on profit over safety, specifically with respect to Trulicity.

56. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television advertisements in January 2022 alone.[40]

57. In another Trulicity television ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of gastroparesis or its sequelae.[41]

58. Similarly, Eli Lilly's promotional website for Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of gastroparesis.[42]

59. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[43]

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[39] Fraiser Kansteiner, *FDA chides Eli Lilly for 2nd misleading ad in 2 months, this time for diabetes blockbuster Trulicity,* Fierce Pharma (Jan. 25, 2022), available at https://www.fiercepharma.com/marketing/fda-chides-lilly-for-second-misleading-ad-2-months-time-for-diabetes-med-trulicity (last visited Nov. 15, 2023).
[40] Ben Adams, *Eli Lilly's Trulicity dethrones Dupixent, taking January's TV ad spending crown,* Fierce Pharma (Feb. 4, 2022), available at https://www.fiercepharma.com/marketing/sanofi-regeneron-s-dupixent-de-throned-as-lilly-s-trulicity-takes-crown-january-s-biggest (last visited Nov. 15, 2023).
[41] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).
[42] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity.
[43] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce

E. The Medical Literature and Clinical Trials Gave Defendants Notice of Gastroparesis Being Causally Associated with GLP-1RAs

60. As previously noted, Ozempic (semaglutide) and Trulicity (dulaglutide) belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

61. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[44]

62. Because the risk of gastroparesis is common to the entire class of drugs, any published literature regarding the association between gastroparesis and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendants on notice of the need to warn patients and prescribing physicians of the risk of gastroparesis associated with these drugs.

63. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[45]

64. Defendants knew or should have known of this risk of gastroparesis from the clinical trials, medical literature, and case reports.

65. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide

[44] Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (visited on 9/26/23).
[45] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (visited on 9/26/23).

group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[46]

66. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376. The cardiovascular outcomes trials included two cases of gastroparesis with the first subject being diagnosed with severe gastroparesis after one month in the trial and second subject being diagnosed with gastroparesis after approximately two months in the trial.

67. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[47]

68. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported

[46] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).

[47] Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (visited on 9/26/23).

reason (64.4%), followed by 'Made me throw up' (45.4%)."[48] As explained above, these are symptoms of gastroparesis.

69. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying and diabetic gastroparesis.

70. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[49]

71. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study

[48] Sikirica M et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

[49] Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, Diabetes Spectr. (2020), Aug; 33(3): 290–297, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (visited on 9/26/23).

warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[50]

72. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[51]

73. An October 2021 article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom

[50] Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).
[51] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (visited on 9/26/23).

onset becomes of the upmost importance." The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[52]

74. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[53]

75. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[54]

[52] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[53] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[54] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).

76. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[55]

77. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[56]

78. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[57]

79. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[58]

80. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[59]

81. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of

[55] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).
[56] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).
[57] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[58] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).
[59] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[60]

82. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[61] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[62] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[63]

83. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell*'"—highlighted three patients who have suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded

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[60] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (visited on 9/26/23).

[61] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (visited on 9/26/23).

[62] Bendix A, Lovelace B Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (visited on 9/26/23).

[63] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html (visited on 9/26/23).

that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis or other severe gastrointestinal issues.[64]

84. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[65]

85. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1RAs. The article noted that the weight-loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the

[64] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).

[65] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed,* CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[66]

86. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[67] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

87. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause gastroparesis and impaired gastric emptying.[68]

88. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies,

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[66] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).

[67] Mohit Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

[68] Cure, *Exenatide and Rare Adverse Events*, N. Eng. J. Med. (May 1, 2008) (https://doi.org/10.1056/nejmc0707137); Rai, *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018) (https://doi.org/10.7759%2Fcureus.3791); Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, Diabetes Ther (2020) (https://doi.org/10.1007%2Fs13300-020-00869-z); Almustanyir, *Gastroparesis With the Initiation of Liraglutide: A Case Report*, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735); Ishihara, *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (Jul. 16, 2022) (https://doi.org/10.7759/cureus.26916); Preda, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, BJS Open (Feb. 2023) (https://doi.org/10.1093%2Fbjsopen%2Fzrac169).

case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

89. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[69]

F. Defendants Failed to Warn of the Risk of Gastroparesis from Ozempic and Trulicity

90. The Prescribing Information for Ozempic (the "Ozempic label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequelae.[70]

91. The Ozempic label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions, including gastroparesis. In fact, gastroparesis is not mentioned at all in the Ozempic label.

92. Instead of properly disclosing gastrointestinal risks, the Ozempic label discloses delayed gastric emptying in the "Drug Interaction" section and notes that Ozempic "may impact

[69] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (visited on 9/26/23).
[70] https://www.novo-pi.com/ozempic.pdf

absorption of concomitantly administered oral medications." Similarly, in the "Mechanism of Action" section, the Ozempic label minimizes gastrointestinal risks by stating that "[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase." These statements only describe the drug's mechanism of action and do not disclose gastroparesis as a ***risk*** of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

93. Similarly, Novo Nordisk's main promotional website for Ozempic (ozempic.com) includes a variety of information about the benefits of Ozempic relating to blood sugar, cardiovascular health, and weight loss, as well as "Important Safety Information" – however, Novo Nordisk does not disclose the risk of gastroparesis within the "Important Safety Information" section of their promotional website.[71]

94. In January 2020, Novo Nordisk removed the "Instructions" portion from Section 17 "Patient Counseling Information" of the Ozempic label, which had instructed prescribers to "[a]dvise patients that the most common side effects of Ozempic are nausea, vomiting, diarrhea, abdominal pain and constipation." These instructions were present in the 2017 and 2019 labels.

95. The 2017 and 2019 labels for Ozempic also instructed physicians that "vomiting … decreases over time in the majority of patients." As a result, a physician would not only fail to appreciate vomiting as a symptom of gastroparesis but, even worse, would encourage a patient to continue using Ozempic despite symptoms of gastroparesis.

96. In its section on "Females and Males of Reproductive Potential," the Ozempic label advises female users to discontinue Ozempic at least 2 months before a planned pregnancy due to the long washout period for semaglutide. This demonstrates that Novo Nordisk knew or should

[71] *See* Ozempic.com (visited on 10/16/23).

have known that symptoms, such as continuous and violent vomiting, can linger long after the drugs are discontinued and shows the need to warn of gastroparesis and its sequelae.

97. From the date Novo Nordisk received FDA approval to market Ozempic until the present time, Novo Nordisk made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis and its sequelae.

98. The Prescribing Information for Trulicity (the "Trulicity label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequelae.[72]

99. The Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as the most common adverse reactions reported in Trulicity patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions, including gastroparesis. While the Warnings and Precautions section indicates that "Use of TRULICITY may be associated with gastrointestinal adverse reactions, sometime severe," the warning is lacking in urgency and specificity.[73]

100. At all times, Trulicity's label has indicated that Trulicity delays gastric emptying and that the delay in gastric emptying "diminishes with subsequent doses." However, Trulicity's label has never warned that Trulicity can cause gastroparesis or its sequelae.

101. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of gastroparesis and continue

[72] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[73] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the Trulicity label state that the delayed gastric emptying caused by Trulicity "is largest after the first dose and diminishes with subsequent doses."[74]

102. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risk of gastroparesis within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website.[75]

103. Nothing in the Trulicity label has ever disclosed gastroparesis as a ***risk*** of taking Trulicity.

104. None of Defendants' other advertising or promotional materials for Ozempic or Trulicity warned prescription providers or the general public of the risks of gastroparesis and its sequelae.

105. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

106. Upon information and belief, Defendants ignored the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae.

[74] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[75] *See* Trulicity.com (last visited Nov. 15, 2023).

107. Defendants' failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae rendered the warnings for Ozempic and Trulicity inadequate.

108. On information and belief, as a result of Defendants' inadequate warnings, the medical community at large, and Plaintiff's prescribing physician in particular, were not aware that Ozempic and Trulicity can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the labels might be sequelae of gastroparesis.

109. On information and belief, had Defendants adequately warned Plaintiff's prescribing physician(s) that Ozempic and Trulicity are causally associated with gastroparesis and its sequelae, then the physician's prescribing decision would have changed by not prescribing Ozempic or Trulicity, or by monitoring Plaintiff's health for symptoms of gastroparesis and discontinuing Ozempic and Trulicity when the symptoms first started.

110. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, which resulted in severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

FIRST CAUSE OF ACTION
(NEGLIGENT FAILURE TO WARN—AGAINST ALL DEFENDANTS)

111. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

112. Texas law imposes a duty on companies who design, manufacture, test, advertise, promote, market, sell, and distribute prescription medications to adequately warn prescribing

physicians of the extent, nature, and severity of the risks of harm posed by their products. At all times mentioned herein, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Ozempic and Trulicity that were prescribed to and used by the Plaintiff.

113. Ozempic and Trulicity were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Defendants.

114. At all relevant times, after approval of Ozempic and Trulicity, and at the times Ozempic and Trulicity left the Defendants' control, Defendants knew or should have known that Ozempic and Trulicity were defective and unreasonably dangerous because the labeling for the prescription medications did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by Defendants.

115. Despite the fact that Defendants knew or should have known that Ozempic and Trulicity caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Ozempic and Trulicity to consumers, including Plaintiff, without adequate warnings.

116. Despite the fact that Defendants knew or should have known that Ozempic and Trulicity caused unreasonably dangerous injuries, Defendants continued to market Ozempic and Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

117. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

118. At all relevant times, given its increased safety risks, Ozempic and Trulicity were not fit for the ordinary purpose for which they were intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and/or to reduce cardiovascular risk in patients with type 2 diabetes.

119. At all relevant times, given its increased safety risks, Ozempic and Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff.

120. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic and Trulicity into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis and its sequelae.

121. At all relevant times, Plaintiff was using Ozempic and Trulicity for the purposes and in a manner normally intended.

122. The Ozempic and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

123. The Ozempic and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including gastroparesis, as well as other severe and permanent

health consequences from Ozempic and Trulicity, they failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote their products, Ozempic and Trulicity.

124. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Trulicity, including the increased risk of gastroparesis and its sequelae.

125. The labels for Ozempic and Trulicity were inadequate because these labels failed to warn Plaintiff's prescribing physician(s) that there was a causal association between these drugs and gastroparesis and its sequelae, based on post-marketing safety data, safety signals, and medical and scientific literature.

126. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

127. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic and Trulicity.

128. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects.

129. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Trulicity, including the increased risk of gastroparesis and its sequelae.

130. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants did not warn Plaintiff's prescribing physicians of all conditions for which a causal association exists, including, but not limited to, gastroparesis and its sequelae.

131. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants failed to warn and/or adequately warn that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.

132. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiff's reliance upon Defendants' warnings was reasonable.

133. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and the physicians' reliance upon Defendants' warnings was reasonable.

134. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis and its sequelae, which are causally associated with Ozempic and Trulicity, they would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

135. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with

adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

136. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae causally associated with Ozempic and Trulicity, Plaintiff would not have used Ozempic or Trulicity and/or suffered from gastroparesis and its sequelae.

137. Had Plaintiff been warned that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, Plaintiff would not have used Ozempic or Trulicity and/or suffered gastroparesis and its sequelae.

138. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae, which are causally associated with Ozempic and Trulicity, Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Ozempic or Trulicity.

139. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic or Trulicity due to the risk of gastroparesis and its sequelae, Plaintiff's prescribing physician(s) would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

140. By reason of the foregoing, Defendants have become liable to the Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic and Trulicity.

141. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health

of consumers and to the Plaintiff in particular, and Defendants are therefore liable for the injuries and damages sustained by the Plaintiff under Texas law.

142. Defendants' inadequate warnings for Ozempic and Trulicity were acts that amount to willful, wanton, grossly negligent, and/or reckless conduct by Defendants.

143. The inadequate warnings in Defendants' drugs, Ozempic and Trulicity, existed when Defendants marketed and sold the drugs to Plaintiff's prescribing physician(s) and/or to Plaintiff and when the drugs were prescribed to Plaintiff.

144. When Defendants marketed and sold Ozempic and Trulicity to Plaintiff's prescribing physician(s) and/or to Plaintiff, the products were unreasonably dangerous because they had defective warnings.

145. The inadequate warnings for Defendants' drugs, Ozempic and Trulicity, were a producing cause of, a proximate cause of, and/or a substantial factor in causing Plaintiff's injuries and damages.

146. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

147. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

148. Plaintiff would show that Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, the connection between Plaintiff's injuries and Defendants' medications until after May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae.

149. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendants owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendants improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae. Accordingly, Defendants fraudulently concealed the existence of Plaintiff's claims.

SECOND CAUSE OF ACTION
(STRICT PRODUCT LIABILITY FAILURE TO WARN – AGAINST ALL DEFENDANTS)

150. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

151. Under Texas law, a company that sells a product in a defective condition unreasonably dangerous to the user or consumer is subject to liability for harm caused to the ultimate user or consumer.

152. Products can be unreasonably dangerous because of a defect in marketing, design, or manufacturing.

153. Texas law imposes a duty on companies who design, manufacture, test, advertise, promote, market, sell, and distribute prescription medications to adequately warn prescribing physicians of the extent, nature, and severity of the risks of harm posed by their products. At all times mentioned herein, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Ozempic and Trulicity that were prescribed to and used by the Plaintiff.

154. Ozempic and Trulicity were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Defendants.

155. At all relevant times, after approval of Ozempic and Trulicity, and at the times Ozempic and Trulicity left the Defendants' control, Defendants knew or should have known that Ozempic and Trulicity were defective and unreasonably dangerous because the labeling for the prescription medications did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by Defendants.

156. Despite the fact that Defendants knew or should have known that Ozempic and Trulicity caused unreasonably dangerous injuries, including, but not limited to, gastroparesis and its sequelae, Defendants continued to market, distribute, and/or sell Ozempic and Trulicity to consumers, including Plaintiff, without adequate warnings.

157. Despite the fact that Defendants knew or should have known that Ozempic and Trulicity caused unreasonably dangerous injuries, including, but not limited to, gastroparesis and its sequelae, Defendants continued to market Ozempic and Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

158. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

159. At all relevant times, given their increased safety risks, Ozempic and Trulicity were not fit for the ordinary purpose for which they were intended.

160. At all relevant times, given their increased safety risks, Ozempic and Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff.

161. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic and Trulicity into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis.

162. At all relevant times, Plaintiff was using Ozempic and Trulicity for the purposes and in a manner normally intended.

163. The Ozempic and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including, but not limited to, gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

164. The Ozempic and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of

the risks of serious side effects, including gastroparesis, as well as other severe and permanent health consequences from Ozempic and Trulicity, they failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote the products.

165. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Trulicity, including the increased risk of gastroparesis and its sequelae.

166. The labels for Ozempic and Trulicity were inadequate because these labels failed to warn Plaintiff's prescribing physician(s) that there was a causal association between these drugs and gastroparesis and its sequelae based on post-marketing safety data, safety signals, and medical and scientific literature.

167. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

168. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic and Trulicity.

169. The labels for Ozempic and Trulicity were inadequate because they did not warn and/or adequately warn of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects.

170. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants failed to warn and/or adequately warn of all possible

adverse side effects causally associated with the use of Ozempic and Trulicity, including the increased risk of gastroparesis and its sequelae.

171. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants did not warn Plaintiff's prescribing physicians of all conditions for which a causal association exists, including, but not limited to, gastroparesis and its sequelae.

172. Communications made by Defendants to Plaintiff's prescribing physician(s) and Plaintiff were inadequate because Defendants failed to warn and/or adequately warn that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.

173. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiff's reliance upon Defendants' warnings was reasonable.

174. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon Defendants' warnings was reasonable.

175. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis causally associated with Ozempic and Trulicity, they would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

176. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks,

including gastroparesis, they would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

177. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Ozempic and Trulicity, Plaintiff would not have used Ozempic or Trulicity and and/or suffered from gastroparesis and its sequelae.

178. Had Plaintiff been warned that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, Plaintiff would not have used Ozempic or Trulicity and/or suffered gastroparesis and its sequelae.

179. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Ozempic and Trulicity, Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Ozempic or Trulicity.

180. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic or Trulicity due to the risk of gastroparesis, Plaintiff's prescribing physician(s) would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

181. By reason of the foregoing, Defendants have become liable to the Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic and Trulicity.

182. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore liable for the injuries and damages sustained by the Plaintiff under Texas law.

183. Defendants' inadequate warnings for Ozempic and Trulicity were acts that amount to willful, wanton, grossly negligent, and/or reckless conduct by Defendants.

184. The inadequate warnings for Defendants' drugs, Ozempic and Trulicity, existed when Defendants marketed and sold the drugs to Plaintiff's prescribing physician(s) and/or to Plaintiff and when the drugs were prescribed to Plaintiff.

185. When Defendants marketed and sold Ozempic and Trulicity to Plaintiff's prescribing physician(s) and/or to Plaintiff, the products were unreasonably dangerous because they had defective warnings.

186. The inadequate warnings in Defendants' drugs, Ozempic and Trulicity, were a producing cause of, a proximate cause of, and/or a substantial factor in causing Plaintiff's injuries.

187. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

188. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

189. Plaintiff would show that Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, the connection between Plaintiff's injuries and Defendants' medications until after May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae.

190. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendants owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendants improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae. Accordingly, Defendants fraudulently concealed the existence of Plaintiff's claims.

THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY – AGAINST ALL DEFENDANTS)

191. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

192. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic and Trulicity as hereinabove described that were used by Plaintiff.

193. At all relevant times, Defendants expressly warranted to Plaintiff's prescribing physician(s) and Plaintiff that Ozempic and Trulicity were safe and effective. Specifically, Defendants expressly warranted to Plaintiff's prescribing physician(s) and to Plaintiff that Ozempic and Trulicity could be safely taken to help treat type 2 diabetes, to reduce cardiovascular risk, and/or for weight loss and did not carry with them an increased risk of gastrointestinal complications, including, but not limited to, gastroparesis. Defendants also expressly warranted to Plaintiff's prescribing physician(s) and to Plaintiff that Ozempic and Trulicity would safely limit how much sugar gets into blood from the liver, that Ozempic and Trulicity would safely and effectively slow down how quickly food leaves the stomach, and that Ozempic and Trulicity would safely and effectively help the pancreas release insulin in response to high blood sugar levels. Defendants also expressly warranted to Plaintiff's prescribing physician(s) and to Plaintiff that Ozempic and Trulicity would safely and effectively lower A1C, reduce cardiovascular risk in patients with type 2 diabetes, and control weight.

194. All of the aforementioned express warranties were made to Plaintiff's prescribing physician(s) and to Plaintiff by way of Ozempic's and Trulicity's labels, websites, advertisements, promotional materials, and through other statements.

195. As a result of Defendants' express warranties to Plaintiff's prescribing physician(s) and to Plaintiff, Plaintiff's prescribing physicians were induced to, and did, prescribe Ozempic and Trulicity to Plaintiff, and Plaintiff was induced to, and did, use Ozempic and Trulicity.

196. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff, would use and/or consume Ozempic and Trulicity based upon their express warranties.

197. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as the Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic and Trulicity based upon their express warranties.

198. At all relevant times, Defendants knew or should have known that Ozempic and Trulicity were unreasonably dangerous because of the increased risk of gastroparesis, especially when the drugs were used in the form and manner as provided by Defendants.

199. At all relevant times, Defendants knew or should have known that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety.

200. The unreasonably dangerous characteristics of Ozempic and Trulicity were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

201. The unreasonably dangerous characteristics of Ozempic and Trulicity were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

202. At the time Ozempic and Trulicity left the Defendants' control, Ozempic and Trulicity did not conform to Defendants' express warranties because Ozempic and Trulicity were not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce cardiovascular risk in patients with type 2 diabetes, or to control weight, in that they were causally associated with an increased risk of gastroparesis.

203. The express warranties made by Defendants regarding the safety of Ozempic and Trulicity were made with the intent to induce Plaintiff to use the products and/or Plaintiff's prescribing physician(s) to prescribe the products.

204. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s) it would be the natural tendency of Plaintiff to use Ozempic and Trulicity and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Ozempic and Trulicity.

205. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express warranties of the Defendants identified herein.

206. Had Defendants not made these express warranties, Plaintiff would not have used Ozempic or Trulicity and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Ozempic or Trulicity and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

207. Plaintiff's injuries and damages were directly and/or proximately caused by Defendants' breach of the aforementioned express warranties.

208. Plaintiff's injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

209. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff.

210. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above-named health consequences.

211. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Ozempic and Trulicity.

212. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

213. Plaintiff would show that Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, the connection between Plaintiff's injuries and Defendants' medications until May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae.

214. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendants owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendants improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after May 1, 2023, when Plaintiff learned that Ozempic and Trulicity may cause gastroparesis and its sequelae. Accordingly, Defendants fraudulently concealed the existence of Plaintiff's claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: April 30, 2025

RESPECTFULLY SUBMITTED,

/s/ Jonathan M. Sedgh

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